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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference CASE 0056		FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/US03/00307	International filing date (day/month/year) 03 January 2003 (03.01.2003)	Priority date (day/month/year) 03 January 2002 (03.01.2002)
International Patent Classification (IPC) or national classification and IPC IPC(7): A61K 39/395, 39/00; G01N 33/53; C12P 21/06, 1/20, 15/00; C07H/21/04; C12N 15/00 and US Cl.: 424/194.1, 130.1; 435/ 7.1; 435/69.1, 225.3, 320.1; 536/23.1, 24.5; 800/21		
Applicant TANOX, INC.		
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>3</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of ___ sheets.</p>		
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of report with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>		
Date of submission of the demand 24 July 2003 (24.07.2003)		Date of completion of this report 20 October 2004 (20.10.2004)
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230		Authorized officer Christina Chan <i>F. Roberts for</i> Telephone No. (571) 272-1600

1. Basis of the report**1. With regard to the elements of the international application:***

- ☒ the international application as originally filed.
- ☒ the description:
pages 1-26 _____ as originally filed
pages NONE _____, filed with the demand
pages NONE _____, filed with the letter of _____.
- ☒ the claims:
pages 27-30 _____, as originally filed
pages NONE _____, as amended (together with any statement) under Article 19
pages NONE _____, filed with the demand
pages NONE _____, filed with the letter of _____.
- ☐ the drawings:
pages NONE _____, as originally filed
pages NONE _____, filed with the demand
pages NONE _____, filed with the letter of _____.
- ☒ the sequence listing part of the description:
pages 1-5 _____, as originally filed
pages NONE _____, filed with the demand
pages NONE _____, filed with the letter of _____.

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(h)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☒ contained in the international application in printed form.
- ☒ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/fig NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. STATEMENT**

Novelty (N)	Claims <u>1-24 and 30-36</u>	YES
	Claims <u>25-29</u>	NO
Inventive Step (IS)	Claims <u>1-24 and 30-36</u>	YES
	Claims <u>25-29</u>	NO
Industrial Applicability (IA)	Claims <u>1-36</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS

Claims 1-24 and 30-36 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the claimed invention.

Claims 25-29 lack novelty under PCT Article 33(2) as being anticipated by Willhem (J. Immunol. Methods May 1995, Vo. 182, No. 1, pages 115-129).

Willhem et al teach a method of producing antibody that binds to mast cell expressed membrane proteins such as CDw17 and CD117/cKit by using mast cell expressed membrane protein as an antigen for producing the reference antibodies (see Materials and methods, in particular). The reference further teaches a method for isolating and purifying mast cell using the reference antibodies (see entire document, page 116, col. 2, in particular). Thus the reference teachings anticipate the claimed invention.

Claims 25-29 lacks an inventive step under PCT Article 33(3) as being obvious over Willhem (J. Immunol. Methods May 1995, Vo. 182, No. 1, pages 115-129).

Willhem et al teach a method of producing antibody that binds to mast cell expressed membrane proteins such as CDw17 and CD117/cKit by using mast cell expressed membrane protein as an antigen for producing the reference antibodies (see Materials and methods, in particular). The reference further teaches a method for isolating and purifying mast cell using the reference antibodies (see entire document, page 116, col. 2, in particular). Therefore, it would have been obvious to of ordinary skill in the art at the time the invention was made to produce any antibody that binds specifically to any antigen expressed on mast cells and then use the antibody isolate and purify mast cells as taught by Willhem et al. One of ordinary skill in the art would have had a reasonable expectation of producing the claimed invention because Willhem et al teach that functionally intact normal human basophils and mast cells can be enriched to homogeneity using the reference method.

Claims 1-36 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

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NOTE OF INFORMAL COMMUNICATION WITH THE APPLICANT

(PCT Rule 66.6)

International application No. PCT/US03/00307	Applicant's or agent's file reference CASE 0056	Date of informal communication (day/month/year) 20 October 2004 (20.10.2004)
Applicant TANOX, INC.		

<u>Communication</u> <input checked="" type="checkbox"/> by telephone <input type="checkbox"/> personal	<u>Participants</u> <input type="checkbox"/> Applicant: <input checked="" type="checkbox"/> Agent: Cheryl A. Liljestrand <input checked="" type="checkbox"/> Examiner(s): Phuong Huynh	<input checked="" type="checkbox"/> Identity checked <input type="checkbox"/> authorization checked <input type="checkbox"/> personally known
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Summary of communication:

Upon request by the examiner, applicant's representative Cheryl A Liljestrand agreed to proceed to the International Preliminary Examination Report (409) in order to meet the administrative deadlines for the instant application.

☐ An extension of time limit is granted (Form PCT/IPEA/427).

☒ A copy of this note is being sent to the applicant with Form PCT/IPEA/429.

PCT/IPEA/424. 416 & 409

Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Phuong Huynh Telephone No. (571) 272-1600 <i>F. Roberto for</i>
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PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:
CHERYL A. LILJESTRAND
TANOX, INC.
10301 STELLA LINK
HOUSTON, TEXAS 77025

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NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of Mailing
(day/month/year) **28 OCT 2004**

Applicant's or agent's file reference

CASE 0056

IMPORTANT NOTIFICATION

International application No.

International filing date (day/month/year)

Priority date (day/month/year)

PCT/US03/00307

03 January 2003 (03.01.2003)

03 January 2002 (03.01.2002)

Applicant

TANOX, INC.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/US

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